5 510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Date prepared:	May 27, 2009

Device Name:

Proprietary name:	CRYOSUCCESS
510(k) number:	K091721
Common name:	cryosurgery unit
Classification name:	878.4350 Unit, cryosurgery and accessories, Class II
Product code:	GEH

Predicate Device:

Substantial Equivalence is claimed with the device, K024009 "CryoProbe", manufactured by H&O Equipments NV/SA on the basis of equivalent intended use / indications for use, technological characteristics and principle of operation.

Device Description:

The CRYOSUCCESS is a hand-held cryosurgical instrument for destroying tissue during surgical procedures by applying cold gas (nitrous oxide, N_2O). The device is based on direct application of nitrous oxide in the liquid phase to the selected treatment area. The N_2O gas is delivered to the treatment site at -89° C to effect cellular destruction (necrosis).

CRYOSUCCES functions by means of heat evaporation upon phase transition, where liquid nitrous oxide (N_2O, laughing gas) is applied to the treatment area by means of a capillary tube at

a constant temperature of -89°C (cold performance) followed by evaporation. The treatment may be invasive.

In general any person may be treated, irrespective of gender or age. The treatment must be performed by medically trained specialists.

Intended Use:

To destroy tissue during surgical procedures by applying extreme cold.

Comparison of Technological Characteristics:

Table 05-1 provides a comparison of the predominant technical characteristics of the new device and the legally marketed predicate device. A more detailed comparison of the devices is presented in section 12-A.

Table 05-1: Comparison of Technological Characteristics

Characteristic	Predicate Device	Device Under Evaluation
Device Name	CryoProbe	CRYOSUCCESS
Models	CryoProbe|c, 1 micro-applicator (information not clear) CryoProbe|x, 3 micro-applicators	Standard tip (Ø = 1mm) Standard tip (Ø = 2mm) Standard tip (Ø = 3mm) Standard tip (Ø = 4mm) Gynecology tip
510(k) Number	K024009	K091721
Cryogen	Nitrous oxide (N_2O, laughing gas), available in 8 g or 16 g cartridges	Nitrous oxide (N_2O, laughing gas), available in 23,5 g cartridge
	Cartridge Pressure: ~50 bar (725 psi)	Cartridge Pressure: 50 bar (725 psi)
	Shelf life: 2 years	Shelf life: 2 years
Shelf life (device)	2 years	5 years (with 2 years warranty)
Treatment temperature	Temperature: Depending on distance of device to lesion, minimum -89°C at contact to lesion	Temperature: constant temperature of -89°C (-128° F) at contact to lesion
Materials	Housing: aluminum	Cryo unit (no housing): brass and stainless steel, gold plated
	Micro-applicator: unknown	Cryotip: metal, gold plated, cryotip in borosilicate glass 3.3 (such as DURAN)
	Lock cap: unknown	Protective cap: thermoplastic rubber
	Filter: unknown	Filter: stainless steel
	O-rings: unknown	Seals: PTFE and acrylonitrile-butadiene-rubber
	Cartridge: metal	Cartridge: metal

Operating Principle	The patented principle of the CryoProbe™ is based upon the direct flow of N_2O in liquid phase for the purpose of freezing with resulting necrosis of tissue in the practice of medicine. To achieve this phenomena a economical gas cartridge is used. The cartridge is filled with liquid N_2O (83%) and the rest with N_2O gas. The liquid N2O is the refrigerant and the N_2O gas is the propellant. The innovation of the CryoProbe™ is the ability to achieve a constant flow of liquid N_2O out of the micro-applicator tip. This is made possible by maintaining the pressure level within the instrument until the liquid N_2O leaves the tip of the micro-applicator, whereupon it will immediately expand.	CRYOSUCCESS functions by means of heat evaporation upon phase transition, where liquid nitrous oxide (N_2O, laughing gas) is applied to the treatment area by means of a capillary tube at a constant temperature of -89°C (cold performance) followed by evaporation. This results in cellular destruction (necrosis) in the treatment area. The amount of gas dispensed is controlled by the medical specialist pressing the lever of the device.
Cleaning / Sterilization	All external parts can be wiped with a cloth soaked in any non-corrosive sterilization solution or alcohol / Whole CryoProbe may be autoclaved	The unit body and cryotips can been cleaned and disinfected with a alcohol-based disinfectant or alcohol / Steam sterilize tips at 134° C (273° F), according to the instruction in the manual of your steam sterilizer and according to the country specific law
Storage	Store in a cool dry place and keep out of the reach of children	Protect the unit against heat and exposure to direct sunlight. The storage temperature is between -10° C and max. +45° C (14° F and max. 113° F).
Maintenance	Change filter with each cartridge, exchange o-rings after frequent autoclaving	No maintenance required, repairs may only be executed by a licensed wholesaler / representative

Summary of Testing:

The relevant requirements set forth in standard ASTM F 882-84 (2002) and the additional requirements specified by the manufacturer are sufficient to assure a safe and effective functioning of the CRYOSUCCESS cryosurgery device. The device has fulfilled the requirements detailed above. The results of the bench testing are summarized in the V&V Plan & Report CRYOSUCCESS enclosed.

Conclusion:

Based on equivalence of intended use / indications for use, technological characteristics and operational principle the applicant concludes, that substantial equivalence between the new and the predicate device has been demonstrated and that the new device, CRYOSUCCESS, is at least as safe and as effective as the legally marketed predicate device, CryoProbe (K024009).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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OCT - 2 2009

Re: K091721
Trade/Device Name: Cryosuccess
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 27, 2009
Received: June 11, 2009

Dear Mr. D'Alessandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091721

Device Name: CRYOSUCCESS

Indications for Use: To destroy tissue during surgical procedures by applying extreme cold.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091721